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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

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12/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,188	JENKINS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-24,26-29 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,11-24,26-29 and 39-41* is/are rejected.

7)☒ Claim(s) *9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 8, 11-24, 26-29 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes with Gibberellin A3 and Gibberellin A3 and A4/A7 mixture, does not reasonably provide enablement for the treatment of diabetes with Gibberellins of Formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The nature of the invention.

Drug discovery is one of the most labor intensive and expensive types of inventions; it can cost over $500 million to bring a single new drug to market.

(B) The state of the prior art.

The art is unaware of successful treatment of diabetes with chemically analogous compounds.

(C) The predictability or lack thereof in the art.

"In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims" (see MPEP 2164.03). In the present case, the specification presents

data showing the effect on blood glucose levels of Gibberellin A3. Based on the evidence of activity limited to Gibberellin A3, it cannot be predicted what other Gibberellins having diverse structural formulas encompassed by the present claims will have similar effect on blood glucose levels as Gibberellin A3.

(D) The amount of direction or guidance present.

The specification discloses a single specific compound and said compound with A4/A7 mixture which has a blood sugar lowering activity. However, this guidance is not commensurate with the full scope of the claims.

(E) Breadth of the claims.

The claims encompass an immense number of species having significant differences in structural formulas. For example, a compound of Formula (1) wherein R1, R2, R3, R4, R5, R6, R7, R8, R9, R10 and R11 are hydrogens is significantly different structurally from the compound of Formula (I) wherein R1 , R2, R3, R5, R7, R8 and R10 are glycosylic ether groups, R4 is C20 alkyl, R6 and R10 are hydroxy groups.

(F) The quantity of experimentation needed.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Applicant's arguments filed November 16, 2007 have been fully considered but they are not persuasive.

Applicant contends that Reeve article summarizes the relative activities of forty exemplary compounds in five separate assays and that eleven compounds relevant to

the claimed invention displayed activity in nearly 80% of the total number of assays in which they were tested. This argument has not been found convincing since the compounds were tested in plant assays and to assays relating the activity of said compounds to biological activity in animals or humans. Further, none of the tested compounds are directed to glycosidic ethers or esters.

Applicant also contends that glucoside conjugates are known in the art and have been isolated as early as 1973. This argument has not been found persuasive since the compounds encompassed by the present claims are not limited to glucoside comjugates. Note hat the term "glycoside" encompass monosaccharides, disaccharides, oligosaccharides and polysaccharides. As noted by applicant, Kren et al disclose that "it is nearly impossible to define the general pattern of biological activities of the glycosides compared to their respective aglycones". Applicant further argues that Kren et al disclose that most glycosides are hydrolyzed by the acidic environment of the stomach or by the action of glycosidases in the small intestine. This argument has not been found persuasive since that claimed methods are not limited to he oral administration but also include rectal, nasal, topical, vaginal or parenteral administration (page 13 of the specification, lines 30-34). Applicant also points out the teaching in Oden that the activity of gibberellin conjugates depends on the hydrolysis to free gibberellins. This argument has not been found persuasive. Oden in column 4, lines 62-67 and in column 5, lines 1-30 discloses examples of glycoside limited to glucose, galactose, arabinose and xylose. All specific compounds disclosed by Oden are limited to glucoside conjugates. However, in the present case, the specification fails to provide

any guidance as to what is meant and encompassed by the term glycoside. Therefore, the term glycoside in the present claims is not limited to monosaccharides, but includes monosaccharides, disaccharides, oligosaccharides and polysaccharides and their numerous derivatives. Therefore, the present claims are still seen to lack enablement.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al (U.S. Patent No. 6,121,317) in combination with Lindenbaum (U.S. Patent No. 5,591,709).

Wu et al disclose gibberellins and their use for wound healing but do not disclose the use of gibberellins in combination with insulin or growth factors. Lindenbaum discloses the use of insulin and growth factors for wound healing (column 2, lines 40-62

and column 3, lines 1-14). Therefore, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to combine gibberellins with insulin or growth factors because such a person would have expected the resulting composition to be useful for wound healing.

Applicant's arguments filed November 16, 2007 have been fully considered but they are not persuasive.

Applicant contends that neither Wu or Lindenbaum teach or suggest the use of Gibberellins to treat diabetes. This argument has not been found persuasive since claims 17-24 and 26-29 are not directed to the treatment of diabetes but are directed to compositions comprising gibberellins combination of insulin or growth factors. In view of the cited prior art, said combination is deemed prima facie obvious for the purpose of wound healing.

Further, in response to applicant's argument that the cited references no not disclose the treatment of diabetes, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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PRIMARY EXAMINER
GROUP 1200